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DIXON, ANNETTE FREDRICKA	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/414,384
Filing Date: October 07, 1999
Appellant(s): CLARK ET AL.

Guy V. Tucker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 30, 2007 appealing from the Office action mailed September 11, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,655,520	HOWE et al.	8-1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howe et al. ('520).

As to claim 21, Howe et al. disclose a device (fig.1a) for controlling the delivery of an aerosolized active agent to the lungs of a human patient, said device comprising a valve (152,153) that provides a high flow resistance of at least 0.4 (cm H2O)1/2/SLM at the onset of the patient's inhalation and that subsequently opens to provide a lower flow resistance (col.3, lines 4-8 and lines 25-33), wherein the lower flow resistance allows for a higher flow rate through the device.

The valve (152,153) of Howe et al. provide a high flow resistance at the onset of a patient's inhalation by closing at least partially (fig.3b) against an inhalation flow rate that exceeds the intended flow rate and subsequently opens (fig.3a) thereby providing a lower flow resistance against an inhalation flow rate that falls below the maximum intended flow rate (col.7, lines 56-64). Inasmuch as the valve of Howe et al. is expressly disclosed as being designed and fabricated to provide specific amounts of resistance to a range of inhalation flow rates and/or inhalation pressures (col.5, lines 11-22; col.7, lines 56-64), it would have been obvious to modify the valve of Howe et al. to exert a

flow resistance of any desired amount including at least 0.4 (cm H2O)1/2/SLM as an obvious matter of design choice because the valve of Howe et al. is expressly disclosed as being fabricated and designed differently for different patient's needs.

As to claims 22 and 23, Howe et al. as discussed above with respect to claim 21 disclose specific customizing of the valve (152,153) to achieve a specific ambient air input to mix with nebulized aerosol (col.5, lines 11-22). It would have been obvious to modify the valve of Howe et al. to exert a high flow resistance of any desired amount including between 0.4 and 2 (cm H2O)1/2/SLM and a low flow resistance of any desired amount including between 0 and 0.3 (cm H2O)1/2/SLM as an obvious matter of design choice because the valve of Howe et al. is expressly disclosed as being fabricated and designed differently for different patient's needs. Howe et al. (fig.3b) is illustrative of a high flow resistance and (fig.3a) is illustrative of a low flow resistance.

As to claims 24 and 25, Howe et al. (col.7, lines 59-60) disclose a flow rate of 0.5 liters per second as an optimum flow rate for adult patients. This translates into 30 liters per minute which is within the claimed range of 15-80 liters per minute during low flow resistance. As a patient inhalation depth increases above this optimum value valve (152,153) exerts more resistance against the patient's inhalation as exemplified by a high flow resistance (fig.3b) thereby limiting the flow rate in proportion to the depth of inhalation to a flow rate including 15 liters per minute.

As to claims 26 and 27, the duration of high flow resistance and/or low flow resistance exerted by the valve (152,153) of Howe et al. varies in dependence upon the duration of a patient inhalation flow rate which exceeds the optimum flow. Therefore, the

valve of Howe et al. will exert a flow resistance for a variable duration of time including 5 seconds or 10 seconds in dependence upon how long a patient is inhaling outside the target rate.

Claims 28-36 are substantially equivalent in scope to claims 21-27 and are included in Howe et al. for the reasons set forth above with respect to claims 21-27.

(10) Response to Argument

Appellant's arguments have been fully considered but they are not persuasive. Appellant asserts: 1) Howe et al. does not teach or fairly suggest all of the recited features, 2) Appellant assets the flow rate within the Howe device is constant, and 3) one of ordinary skill in the art at the time the invention was made would not have found it obvious to make the modifications to Howe et al. to meet the recited claim limitations. Examiner respectfully disagrees with Appellant's assertions.

Regarding Appellant's first assertion, Howe et al. discloses a multi-phase operation of a breathing device, wherein the breathing device operates during strong inhalation with a high resistance and during weak inhalation with a low resistance. As addressed in the response to arguments section of Final Rejection, mail date September 11, 2006, "Upon reducing the strength of their inhalation (enough to permit the inhalation valve to at least partially open as illustrated in Figure 3b), it is clear that the valve would open (at least partially) and provide a lower flow resistance thereby allowing a higher flow rate (Column 5, Lines 3-5) through the device as illustrated in Figure 3b of Howe et al." Appellant's current claim language does not require the

change in flow to occur at a specific point in time. Appellant's claims simply recite a high resistance during the onset of inhalation and a lower flow resistance available at some time later. Intrinsically, this later time in the future includes exhalation of the patient.

Regarding Appellant's second assertion, Appellant's asserts there is a constant flow rate within the device of Howe (Page 6 of Appellant's Appeal Brief). Further, Appellant asserts this functionally presents a distinction between the prior art made of record and the instant invention. However, it should be noted that Howe explicitly states the output flow rates of the device to not need to remain a constant value. (Column 5, Lines 17-19). Furthermore, upon further examination of Appellant's arguments, it appears the Appellant is equating the constant flow rate through the device with the output flow rate of the device. Yet, this method of equating is improper as the flow rate through the device incorporates the input flow, the flow through the nebulizer, and output flow of the device. Therefore, the terms flow rate through the device and output flow rate are not the same. Finally, as noted in the response to the first assertions, Howe explicitly states the changes in flow are a function of the inhalation speed and resistance of the device

Regarding Appellant's third assertion, Howe et al. explicitly states the operational thresholds of the valve may be varied based upon the wall angles, orifice size, length and material properties in order to customize the operation of the breathing device to the patient's inhalation pressures. (Column 5, Lines 10-24). Intrinsically, this variability

in operation in response to the specific patient requirements teaches the obviousness to modify the device of Howe et al. to meet the needs of the patient.

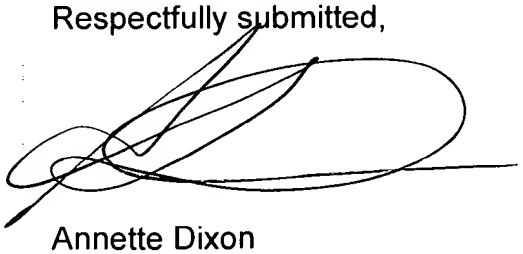
In conclusion, because of the aforementioned reasons, the rejection of claims 21-36 has been maintained. Furthermore, in regards to Appellant's assertions of independent claims 21, 32, and 38 as the subject matter of these claims are coextensive and similar in scope, the aforementioned reasoning applies.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



Annette Dixon

Examiner, Art Unit 3771

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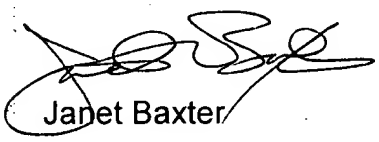
Justine Yu

Supervisory Primary Examiner, Art Unit 3771



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